A RETROSPECTIVE STUDY ON PRESCRIBING PATTERNS AND COST ANALYSIS OF PROTON PUMP INHIBITORS

A Dissertation Submitted to
THE TAMILNADU Dr. M.G.R MEDICAL UNIVERSITY,
Chennai-600 032

In partial fulfillment of the requirements for the award of the Degree of
MASTER OF PHARMACY
IN
PHARMACY PRACTICE

Submitted By
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PSG COLLEGE OF PHARMACY
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OCTOBER 2017

Certificates

CERTIFICATE

This is to certify that the dissertation entitled **"A Retrospective study on prescribing patterns and cost analysis of proton pump inhibitors"** submitted by **University Reg. No. 261540652** is a bonafide work carried out by the candidate under the guidance of **Dr. Prudence A Rodrigues, M. Pharm.,Ph.D,** and submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment of the Degree of **Master of Pharmacy** in **Pharmacy Practice** at the Department of Pharmacy Practice, PSG College of Pharmacy, Coimbatore, during the academic year 2015-2017.

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Place: Coimbatore **Dr.Prudence A Rodrigues,M.Pharm., Ph.D,**

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DECLARATION

I do hereby declare that he dissertation work entitled **"A Retrospective study on prescribing patterns and cost analysis of proton pump inhibitors"** submitted to The Tamil Nadu Dr.M.G.R. Medical University, Chennai, in partial fulfillment for the Degree of **Masters of Pharmacy** in **Pharmacy Practice**, was done by me under the guidance of **Dr. Prudence A Rodrigues., M. Pharm., Ph.D,** at the Department of Pharmacy Practice, PSG College of Pharmacy, Coimbatore, during the academic year 2015 – 2017.

Reg.No:261540652

EVALUATION CERTIFICATE

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Examination Centre: PSG College of Pharmacy, Coimbatore.

Date:

Internal Examiner **External Examiner**

Convener of Examination

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Dedicated to Almighty,

My Beloved Parents

&

My Respectful Guide

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Abstract

ABSTRACT

Background: PPIs are the most commonly used drugs in clinical practice; inappropriate prescribing may result in increased therapeutic load and treatment cost as well. Hence, a study was conducted to determine the prescribing pattern (rationality and irrationality) of both iv and oral PPIs in tertiary care teaching hospital and cost minimization process can be used only to compare two products that have been shown to be equivalent in dose and therapeutic effect.

Aim and Objective:

- To analyze the prescribing pattern of Proton pump inhibitors.
- To assess the rationality of prescribing oral and iv Proton pump inhibitors.
- To estimate the cost of iv and oral Proton pump inhibitors.

Method: A retrospective observational study was carried out in a multispecialty tertiary care hospital on patients' medical records from Department of Gastroenterology and Department of general surgery. The study sample size were 341, the exclusion criteria were patients who did not receive Oral and IV PPIs and patients under 18 years old. The cost of the prescribed PPI brands is compared with the cost of other available brands in the hospital pharmacy.

Results: Most of the patients were seen under the age category between 41-60 years (62.8%). The majority of the patients were Male in this study (69.5%). Most of the patients were included from the Department of Gastroenterology (63.3%). Pantoprazole was administered in a majority of 308 patients (90.3%). Indication for giving PPIs in 181 Patients were Multi-drug use (53.1%) which was majority. 208 patients received PPI through intravenous route (61%). Most of the patients in the study received PPI for a duration of 4 days in 65 patients (19.1%). 282 patients received rational therapy (82.7%) which was a greater extent. Pan 40 (Pantoprazole) was seen to be the most prescribed brand in this study. The cost of pan 40 was reasonable compared to the other prescribed brands. However, Omez (Omeprazole) was the prescribed brand with least cost.

Conclusion: Pantoprazole was the most prescribed PPI in this study. There are only considerable differences between PPIs in terms of clinical efficacy, the possible drug interactions could be a key factor in the selection of PPIs. In addition, utmost care should be taken while administering PPIs in patients receiving multiple drugs and other elder patients prone to take combination of drugs to attain a rational therapy. PPIs proven to have lower risks of drug interaction would be the favorable choice in those occasions.

Introduction

INTRODUCTION

Proton Pump Inhibiitors (PPIs) remain the superior choicein the evidence-based treatment of gastrointestinal disorders which include peptic ulcer disease (PUD), dyspepsia, gastro esophageal reflux disease (GERD),eradication of Helicobacter pylori (in combination with antibiotics), controlling excessive acid secretion in Zollinger–Ellison syndrome and hypersecretory state, and prevention of ulcers due to nonsteroidal anti-inflammatory drugs (NSAIDs).They are also used for a number ofunlicensed indications (morecommon in hospital settings), including the reduction of re-bleeding episodes aftertreatment of severe peptic ulcer bleeding, prophylaxis of acid aspiration during generalanesthesia and stress ulcer prophylaxis.[1]

PPIs class includes the following drugs: Lansoprazole, Omeprazole, Pantoprazole,Rabeprazole and Esomeprazole.The differences between the PPIs in terms of clinicalefficacy and safety are fairly minimal.

A) Indications of PPIs:

PPIs are prescribed for the previously mentioned indications, but when a patient presented with dyspepsia are initially prescribed non-pharmacological therapy, such as to follow simple lifestyle changes which include weight reduction, healthy eating, smoking cessation and avoiding diet or beverage ingredients that associated with stimulation of dyspepsia such as alcohol, coffee, chocolate and fatty foods. It's strongly recommended that the patient should eat well before 3 to 4 hours from bedtime and raise the head of the bed may also be beneficial. If the response in not well enough, the first line treatment should be alginate either "as required" or regularly. PPIs should only be prescribed for short courses (4 weeks) where needed. If symptoms persist or recur, a PPI can be continued at the lowest dose possible to control symptoms or on basis of as-required.

PPIs are generally well tolerated, and the side effects are usually mild and reversible, including headache, diarrhea, abdominal pain, nausea, constipation, skin rashes and dizziness. There are, however, growing concerns about a variety of adverse effects with long term PPI use as listed as following:[2]

1) Vitamin B_{12}Deficiency
2) Vitamin C deficiency
3) Mineral deficiencies:
    I. Calcium deficiency
    II. Magnesium deficiency
    III. Iron deficiency
4) Rebound hypersecretion syndrome
5) Risk of Acute interstitial nephritis (AIN)

1) **Vitamin B_{12}Deficiency:**

The main food sources for vitamin B_{12} (water-soluble vitamin) include meats, fish, poultry, eggs and dairy products. Vitamin B12 absorption depends on peptic enzymes to cleave dietary $B_{12}$from dietary proteins. This process is performed primarily by pepsin, which needs gastric acid for its activation from pepsinogen precursor. Without gastric acid, vitamin B_{12}would not be cleaved from dietary protein and would not be able to bind to R-proteins, which in turn protect vitamin $B_{12}$from pancreatic digestion. Theoretically, acid suppression may lead to malabsorption and eventually vitamin B_{12}deficiency. But the common human storage of the vitamin B_{12} is quite enough to be depleted minimum more than one year. It has been estimated that vitamin B_{12} deficiency affects up to 20% of the elderly, and has been linked to impaired gastrointestinal absorption syndromes and pernicious anemia. The results from these trials have not yielded consistent data to create either therapeutic guidelines or to offer recommendations for routine dietary supplementation.

2) **Vitamin C deficiency:**

PPIs affect vitamin C bioavailability through decreasing its concentration in gastric juices and its proportion of vitamin C in its active antioxidant form, ascorbic acid. A previous study investigated the effect of omeprazole 40 mg for 4 weeks on vitamin C

concentrations in gastric juice in both healthy individuals and subjects. Median intragastric pH increased from 1.4 before omeprazole therapy to 7.2 while subjects were taking omeprazole, and vitamin Cconcentrations decreased from 5µm/l to 3µm/l reflecting a notable decrease in the biologically active form of ascorbic acid.

3) **Mineral deficiencies**

I- Calcium deficiency

There is conflicting evidence regarding to the role of intragastric hydrochloric acid in calcium absorption. In one study proposed that both stomach acid and the slightly acidic medium of the proximal duodenum are important to facilitate calcium dissociation from ingested food, making it available for absorption. In The contrary in another study found that gastric acid secretion and gastric acidity do not normally play a role in the absorption of dietary calcium. Several trials implicating treatment with PPI as leading to an increased risk of osteoporotic fracture has raised a critical analysis of the possible relationship, suggesting a causal relationship. In 2010, the US FDA released a warning revising the prescription and OTC labels for PPIs to include new safety information regarding a potential increased risk of fractures of the hip, wrist and spine with the use of these medications.

II- Magnesium deficiency:

All PPIs has been reported and documented to cause hypomagnesaemia that are biochemically substituted pyridyl-methylsulphonylbenzimidazadole derivatives, in the following order of potency: Rabeprazole, Esomeprazole, Omeprazole, Lansoprazole and Pantoprazole. In 2011, the US FDA released a warning based upon several published case reports stating that PPIs may cause hypomagnesaemia if taken for more than one year.

III- Iron deficiency:

It has been reported that PPI therapy results in clinically significant iron malabsorption due to gastric acid hyposecretion. Dietary iron is present in food in either the following forms; heme iron (32%) or nonheme (66%), and absorption of nonheme iron is markedly improved by gastric acid. The role of gastric acid assists

food sources containing nonheme iron to dissociate and to solubilize the iron salts, resulting in formation of complexes with sugars and amines facilitating absorption.

4) **Rebound hypersecretion syndrome:**

NICE confirms that long term treatment with PPI has been linked to rebound hypersecretion,and states that: "This may exacerbate symptoms once PPI therapy is discontinuedalthough this is a theoretical concern as there are no data that support acid rebound as a clinical problem in patients". Therefore it is recommended that all patients receiving PPIs should be offered anannual review and are encouraged to taper down from treatment gradually where appropriate.

5) **Risk of Acute interstitial nephritis (AIN):**

AINis an uncommon side effect of PPIs. In a previous study undertaken in four cases where the following PPIs were implicated (pantoprazole omeprazole and esomeprazole in one each), AIN developed after an average period of 4 weeks of drug therapy. PPI was stopped and steroids were initiated in all patients. ANI was successfully reversed totally in two patients and partial in the rest two. So an attention is needed to suspect ANI induced by PPIs.[(5)]

B) Prescribing patterns and rational prescribing[(3)]

It is known that rational prescribing of medication is assurance that the patient receives the appropriate medication according to his/her medical needs in a dose and route of administration meet the condition requirement for adequate period of time. In previous study had reported that prescribing of PPIs was estimated over 60% were for hospitalized patients. The Medical council of India in a notification at New Delhi, in 11th of March-2002, clearly stated that every physician should prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs.

The comparison in the difference in the efficacy between oral versus intravenous PPIs was done by a pervious study in the treatment of peptic ulcer treatment. This study

reached for the result that oral PPIs demonstrated similar effectiveness to intravenous PPIs among patients with peptic ulcer bleeding.

Over prescribing of IV PPIs is associated with in increased shortages of IV PPIs in hospitals, therapeutic burden on patients, increased frequency of adverse effects, and increased treatment costs. A study examined the inappropriate use of intravenous PPIs .The result showed that there was significant inappropriate PPIs administration with reference to indication to use, duration of therapy, and changeover of therapy.

Methods to evaluate patterns of drug use in hospitals:

- Prescription and physician surveys,
- Analysis of drug sales or drug consumption data,
- Reviews of medical records.

C) Pharmacoeconomics

Pharmacoeconomics is the science concerned with the comparisons of costs & consequences/outcomes of drug therapies. It adopts and applies principles and methodology of health economics.Pharmacoeconomics is essential for pharmaceutical policy and decision making. And it can be used effectively by a pharmacist to improvise the efficiency of his profession.[6]

Types of Pharmacoeconomics Analysis:

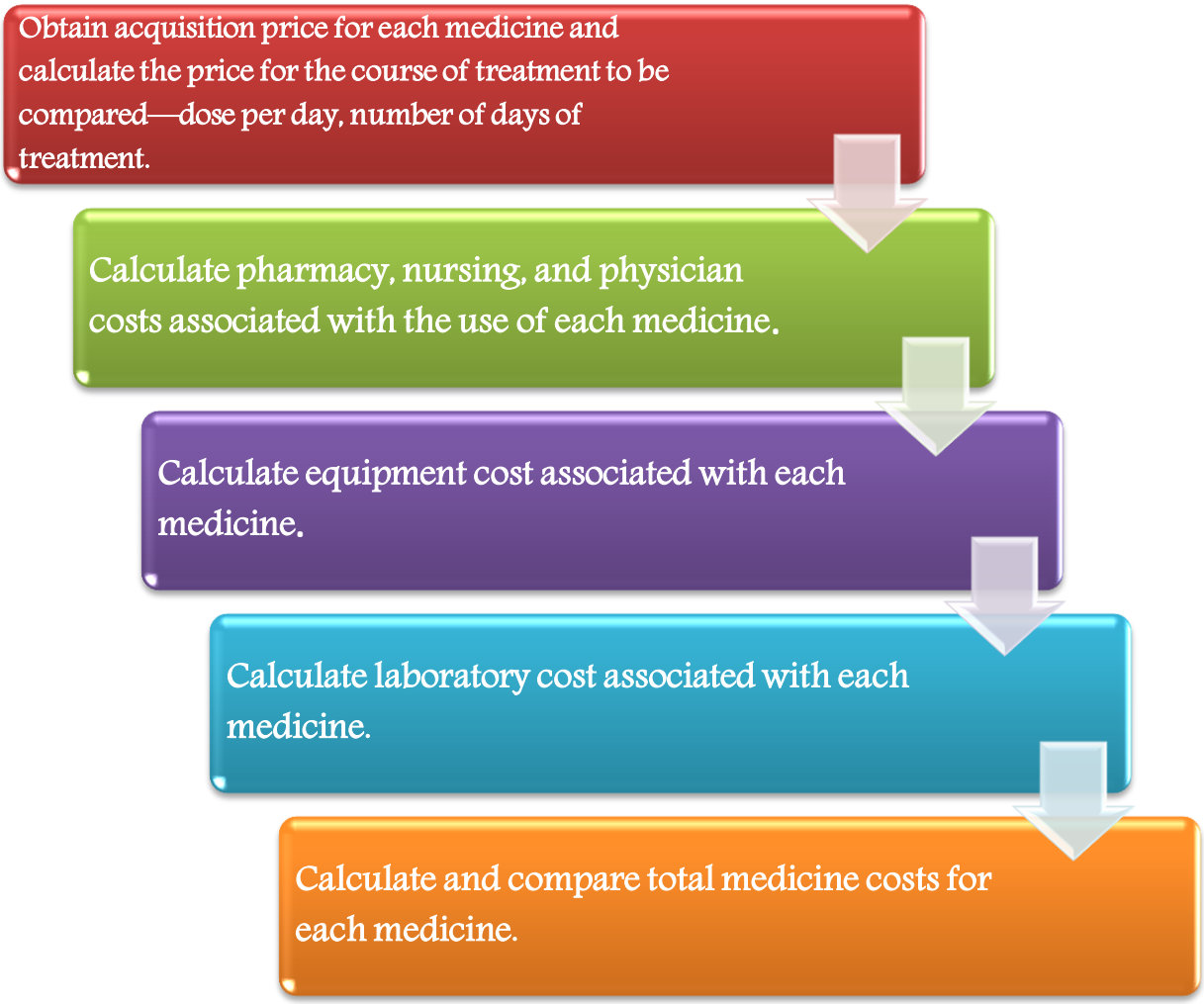
1) Cost Minimisation Analysis(CMA).
2) Cost Effective Analysis (CEA)
3) Cost Utility Analysis (CUA).
4) Cost Benefit Analysis (CBA).

Cost analysis of PPIS:

The most commonly used cost analysis is Cost-Minimization Analysis (CMA) which simply compare two the price of two medicines with equal effectiveness. CMAis

accurate method when comparing cost between two therapeutically equivalent medicines. The following diagram demonstrate the steps of CMA.

Steps of CMA



Background

BACKGROUND

PPIs are the most commonly used drugs in clinical practice; inappropriate prescribing may result in increased therapeutic load and treatment cost as well. Hence, a study was conducted to determine the prescribing pattern (rationality and irrationality) of both iv and oral PPIs in tertiary care teaching hospital and cost minimization process can be used only to compare two products that have been shown to be equivalent in dose and therapeutic effect.

There is growing concern with the rapid increase in prescribing proton pump inhibitor drugs (PPIs), (In 2006 PPI was the third most frequently prescribed drug in Australia. In United States, UK and New Zealand similar trends were observed), for a variety of gastrointestinal disorders, (gastro-esophageal reflux disease, dyspepsia, peptic ulcer disease, NSAID-induced ulcer, eradication of Helicobacter pylori, and hyper secretory disorders), and the escalating costs associated with this trend. The study have included that general practitioners (GPs) prescribe PPIs irrationally and that patients demand PPIs and use them as a way of avoiding having to make lifestyle changes. The present study was planned with the aim of finding out the rational use of proton pump inhibitors (PPIs) in the patients.

A retrospective observational study of PPIs was conducted for a period of six months in the patients of gastroenterology and surgery departments who were more than 18 years of age and who were receiving i.v and oral (PPIs) were included in the study; paediatric patients and out patients were not enrolled in the study. All the details of each patient was collected from patient's case notes, treatment chart and evaluated for appropriateness regarding indications.

Literature Review

LITERATURE REVIEW

1- **Nasrin Shahsavani, D. R Raju Koneri, Balakeshawa Ramaiah, Shibi Mary Thomas, Assessment of prescribing Pattern of proton Pump inhibitor and histamine 2 receptor antagonist, Journal of Innovations in Pharmaceuticals and Biological Sciences, e-ISSN: 2349-2759 p-ISSN: 2395- 1095**

Proton Pump Inhibitors (PPIs) remain the leading evidence based therapy for upper Gastro intestinal disorders, including gastro-esophageal reflux disease, dyspepsia, peptic ulcer disease, NSAID-induced ulcer, eradication of Helicobacter pylori, and hyper secretory disorders. H2 receptor antagonists like ranitidine is the first choice H2 receptor antagonist in most patient. Our study aimed about the assessment of the prescribing pattern of PPIs and H2 receptor blockers. Our other objectives were to assess therapeutic appropriateness with standard guideline, ADR &Drug Interactions related to PPI &H2 receptor antagonist. Our study was a prospective observational study, included 209 patients, was conducted in a tertiary care Bangalore Baptist Hospital, Bangalore, INDIA for a period of six months. The results of this study observed that males were more using PPIs than females. Therapeutic appropriateness was mostly correct among both PPIs and H2 receptor blockers. We can conclude that continuous medical education with focus on rational drug use and evidence based medicine should form part of the program of the hospital. They should be involved in collection and presentation of prescribing data as part of clinical audit and also education of patients/caretakers. Also hospitals should consider developing controlled policies like formulary restriction, stop orders for specific indications, and automatic switch-order to oral PPI if patient is receiving oral feeding. This study could provide direction for much needed randomized controlled trials evaluating the use of PPIs in the first year of life, including specific recommended dosing, duration of therapy, and effectiveness of treatment.

2- **K. Sampathkumar, R. Ramalingam, A. Prabakar, and A. Abraham, Acute interstitial nephritis due to proton pump inhibitors, Indian J Nephrol. 2013**

Proton pump inhibitors (PPI) are commonly prescribed for dyspepsia and acid peptic disease. Acute interstitial nephritis (AIN) is an uncommon though important sideeffect of these classes of drugs. We describe four cases: three females and one male. PPIs implicated were pantoprazole in two, omeprazole and esomeprazole in one each. AIN developed after an average period of 4 weeks of drug therapy. The symptoms were vomiting, loin pain, and oliguria. Minimal roteinuria with pyuria were seen and the mean serum creatinine was 4.95 ± 4

mg/dl. Two patients required hemodialysis. Renal biopsy showed interstitial mononuclear, plasma cell and eosinophilic infiltrates in all cases. PPI was stopped and steroids were started in all. Renal recovery was total in two and partial
in two. A high index of suspicion is required to diagnose PPI induced AIN. Renal biopsy for confirmation followed up by prompt steroid therapy results in renal functional improvement.

3- **Elaine W. Yu, MD1, Scott R. Bauer, BS2, Paul A. Bain, PhD3, and Douglas C. Bauer, MD4, Proton pump inhibitors and risk of fractures: a meta-analysis of 11 international studies, NIH Public Access, Am J Med. 2011 June ; 124(6): 519–526.** doi:10.1016/j.amjmed.2011.01.007.

In this meta-analysis of observational studies, PPIs modestly increased the risk of hip, spine, and any-site fractures, whereas H2RAs were not associated with fracture risk. The possibility of residual confounding cannot be excluded. Further skeletal evaluation should be considered for patients who are taking PPIs and are also at risk for osteoporotic fracture.

4- **K. K. F. Tsoi*,†,‡, H. W. Hirai* & J. J. Y. Sung*, Meta-analysis: comparison of oral vs. intravenous proton pump inhibitors in patients with peptic ulcer bleeding, Alimentary Pharmacology and Therapeutics, 2013; 38: 721-728 [a] 2013 John Wiley & Sons Ltd**

Oral PPIs demonstrate a similar effectiveness to intravenous PPIs among patients with peptic ulcer bleeding, but the results were combined from open-labelled trials with limited sample size. A large double-blind noninferiority trial is required to better assess the role of oral PPIs.

5- **Joel J. Heidelbaugh, Proton pump inhibitors and risk of vitamin and mineral deficiency: evidence and clinical implications, Therapeutic Advances in Drug Safety, (2013) 4(3) 125–133**

Proton pump inhibitors (PPIs) remain the superior choice worldwide in antisecretory therapy in the evidence-based treatment of upper gastrointestinal disorders including gastroesophageal reflux disease, erosive esophagitis, dyspepsia and peptic ulcer disease. PPI overutilization in ambulatory care settings is often a result of failure to re-evaluate the need for continuation of therapy, or insufficient use of on-demand and step-down therapy. Nonjudicious use of PPIs creates both preventable financial as well as medical concerns. PPIs have been associated with an increased risk of vitamin and mineral deficiencies impacting vitamin B12, vitamin C, calcium, iron and magnesium metabolism. While these risks are considered to be relatively low in the general population, they may be notable in elderly and malnourished patients, as well as those on chronic hemodialysis and concomitant PPI therapy. No current evidence recommends

routine screening or supplementation for these potential vitamin and mineral deficiencies in patients on either short- or long-term PPI therapy. Reducing inappropriate prescribing of PPIs can minimize the potential risk of vitamin and mineral deficiencies.

6- **Jarchow-Macdonald AA[1], Mangoni AA, Prescribing patterns of proton pump inhibitors in older hospitalized patients in a Scottish health board, , 2013 Oct;13(4):1002-9Geriatr Gerontol Int.**

Inappropriate PPI prescribing is common in frail older hospitalized patients, and might increase the risk of drug-drug interactions. Polypharmacy and comorbidity were independently associated with inappropriate PPI prescribing in this group.

7- **P. F. Haastrup, Rasmussen , J. M. Hansen ,R. D. Christensen , J. Søndergaard and D. E. Jarbøl General practice variation when initiating long-term prescribing of proton pump inhibitors: a nationwide cohort study, *BMC Family Practice*BMC series, 2016**17**:57**

Practice characteristics such as GP age and gender could explain some of the observed variation in prescribing patterns for PPIs. This variation may indicate a potential for enhancing rational prescribing of PPIs.

8- **Mark Reid, MD1,2*, Angela Keniston, MSPH1, Inappropriate Prescribing of Proton Pump Inhibitors in Hospitalized Patients, Journal of Hospital Medicine Vol 7 | No 5 | May/June 2012**

Proton pump inhibitors are frequently inappropriately prescribed to Medicine inpatients who do not have a valid indication and this practice is associated with an increase in C. difficile infection. Interventions are needed to curtail this inappropriate prescribing practice.

9- **N.M. Walker, J. McDonald, An evaluation of the use of proton pump inhibitors, *Pharmacy World and Science*, June 2001, Volume 23, Issue 3, pp 116–117**

Frequent review of therapy and improved communications between primary and secondary care are vital to rationalise the use of PPIs and to reduce expenditure.

10- **Soumana C Nasser, Jeanette G Nassif, and Hani I Dimassi, Clinical and cost impact of intravenous proton pump inhibitor use in non-ICU patients, World J Gastroenterol. 2010 Feb 28; 16(8): 982–986**

This study highlights the over-utilization of IV PPIs in non-intensive care unit patients. Restriction of IV PPI use for justified indications and route of administration is recommended.

11- **Mohammed S. Alsultan, Ahmed Y. Mayet, Areej A. Malhani, and Mashael K. Alshaikh' Pattern of Intravenous Proton Pump Inhibitors Use in ICU and Non-ICU Setting: A Prospective Observational Study**

Inappropriate IV PPI utilization was predominant in non-ICU patients, mostly for stress ulcer prophylaxis that leads to a waste of resources. Applying appropriate policies, procedures and evidence-based guidelines, educated physicians and surgeons can clearly limit inappropriate IV PPI use.

12- **Joanna K. Law, Chris N. Andrews, Robert Enns, Intravenous proton pump inhibition utilization and prescribing patterns escalation: a comparison between early and current trends in use,GIE, Volume 69, Issue 1**

IV PPI use has escalated at our hospital and is being prescribed in patients before endoscopy with fewer patients noted to have HRES on endoscopy.

13- **Jacob G. Hoove, Annabel L. Schumaker, Kevin J. Franklin, Use of Intravenous Proton-Pump Inhibitors in a Teaching Hospital Practice, *Digestive Diseases and Sciences*, September 2009, Volume 54, Issue 9**

Intravenous PPI prescribing habits in this military hospital facility are poor. A multifaceted approach including physician/pharmacist education, IV PPI ordering templates, and a consensus medical position statement from a major gastroenterological or prominent medical association may lead to more appropriate use.

14- **Mandana Moradi, Samaneh Raeesi and Zahra Sepehri' Audit of IV pantoprazole: pattern of administration and compliance with guideline in a teaching hospital, , SpringerPlus*SpringerPlus*20165:1749**

We concluded that although establishing guideline was successful in reducing the overall rate of IV pantoprazole administration and its related costs, different contributing factors halted its effect on correcting the prescribed dosage and indications, especially as the time gaps from guideline establishment. This fact magnifies the importance of continuous educations of prescribers about the importance of evidence based practice and need for and implementing a powerful executive supervisory in our hospital.

15- **Ghias Ul Hassan, Israr Ul Haque*, Muhammad Asim Hameed, PRACTICES OF PROTON PUMP INHIBITORS USE IN MEDICAL WARDS, Pak Armed Forces Med J 2017; 67 (4): 524-28**

PPIs are over used without clear indications in hospitalized and discharged patients.

Aim & Objectives

AIM AND OBJECTIVE

The study is concerned with monitoring of PPI prescribing patterns in order to:

- To analyze the prescribing pattern of proton pump inhibitors
- To assess the rationality of prescribing oral and iv proton pump inhibitors
- To estimate the cost of the iv and oral proton pump inhibitor

Plan of Study

PLAN OF STUDY

PHASE I:

- Preliminary literature search
- Designing study protocol
- Data collection form

PHASE II:

- Literature survey
- Data collection
- Data analysis

PHASE III:

- Result and discussion

Methodology

METHODOLOGY

Study design:

Retrospective observational study.

Study location:

The study was carried in a multispecialty tertiary hospital, on inpatients medical records from gastroenterology and surgery ward.

Study Approval:

The protocol of study submitted to institution of human ethics committee (IHEC,PSG IMSR) of the hospital. The protocol was approved with proposal number: 17/153 on 25.04.2017 .

Sample size:

341 patients who received PPIs.

The total number of patients in the respected two wards who was prescribed PPI was 2987 patient for the period of six months. By applying the RAOSFT program the sample size calculated to be 341 patient with the margin of error 5% and confidence level of 95%.

Study duration:

Six months.

Inclusion criteria:

- Male and female patients
- Patients received oral/ IV PPI
- Patient over 18 years old

Exclusion criteria:

- Patients don't receive oral and IV PPI.
- Patient under 18 years old

Methodology:

Recruitment of subjects according to the inclusion and exclusion criteria

Data collection

Analyze the PPI,s

Assess the rationality

Cost benefit studies

Result and conclusion

Statistical analysis:

The data was analyzed by Percentage analysis.

Results

RESULTS

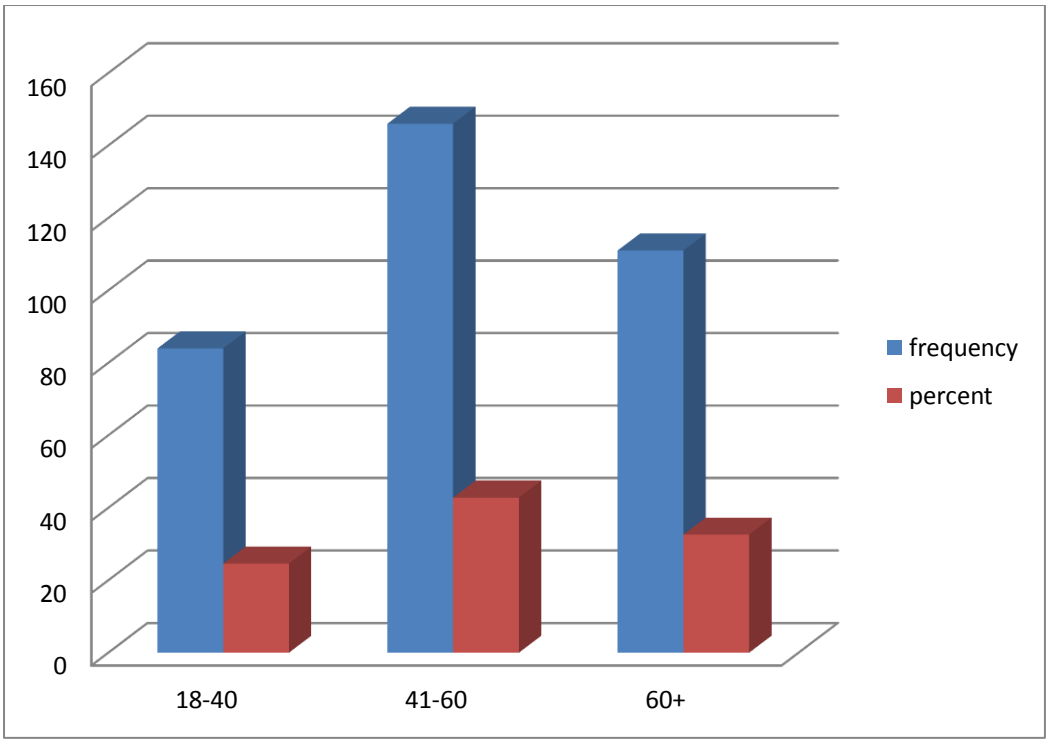
AGE

The study included 341 patients. Out of them, 146 patients were observed from the age group between 41-60 years old (42.8%), then 111 patients were above 60 years old (32.8%) and 84 patients of age between 18-40 years (24.6%). Most of the patients were seen under the age category between 41-60 years.

Table-1: Age wise distribution

Age	Frequency	Percent
18-40	84	24.6
41-60	146	42.8
60+	111	32.6

Figure-1: Age category v/s Frequency and percent



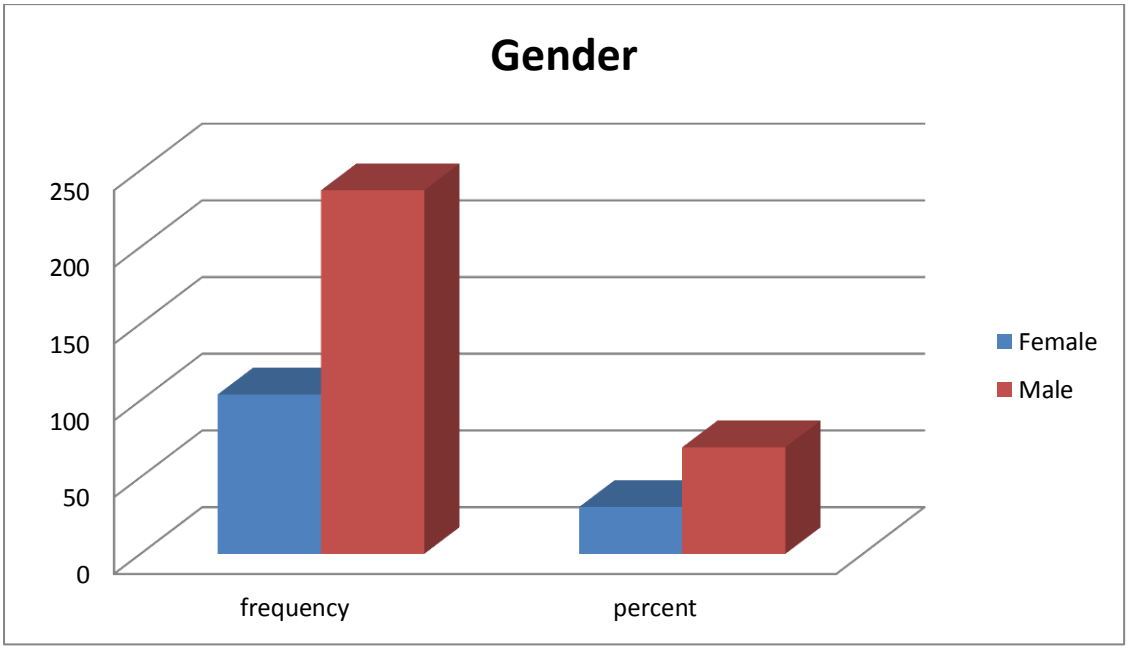
Gender

Out of 341 patients in the study, 237 patients were Male (69.5%) and 104 patients were female (30.5%). The majority of the patients were Male in this study.

Table-2: Gender

Gender	Frequency	Percent
Female	104	30.5
Male	237	69.5

Figure-2: Gender v/s Frequency and percent



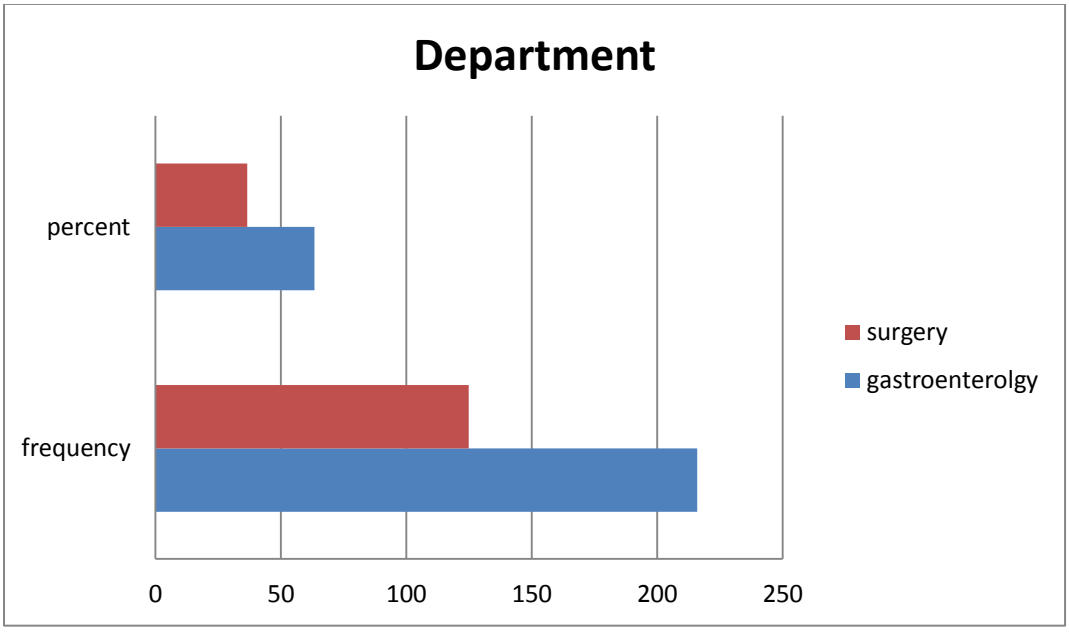
Department

Among 341 patients included in this study, 216 patients were from Department of Gastroenterology (63.3%) and remaining 125 were from Department of Surgery (36.7%). Most of the patients were included from the Department of Gastroenterology.

Table-3: Department

Department	Frequency	Percent
Gastroenterology	216	63.3
Surgery	125	36.7

Figure-3: Department v/s Frequency and distribution



PPI used

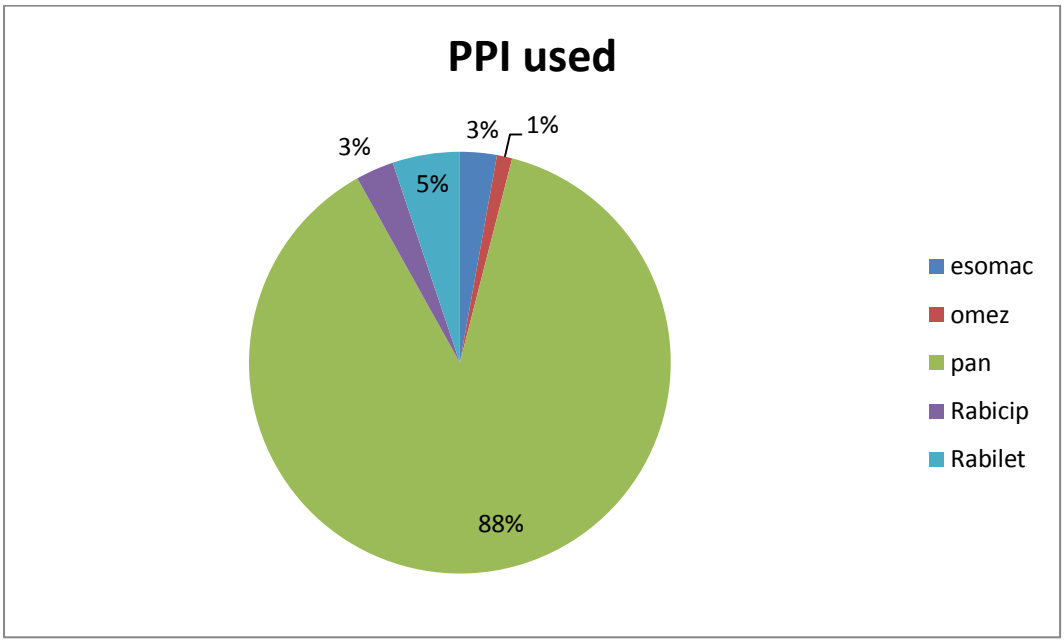
Among 341 patients in the study, Pan was administered in 308 patients (90.3%) followed by Rablet in 18 patients (5.3%), Esomac in 10 patients (2.9%), Omez in 4 patients (1.2%) and Rabicip in 1 patient (0.3%).

Table-4: PPI used

Name of PPI	Frequency	Percent
Esomac	10	2.9

Omez	4	1.2
Pan	308	90.3
Rabicip	1	0.3
Rablet	18	5.3

Figure-4: PPI used v/s Frequency and percent



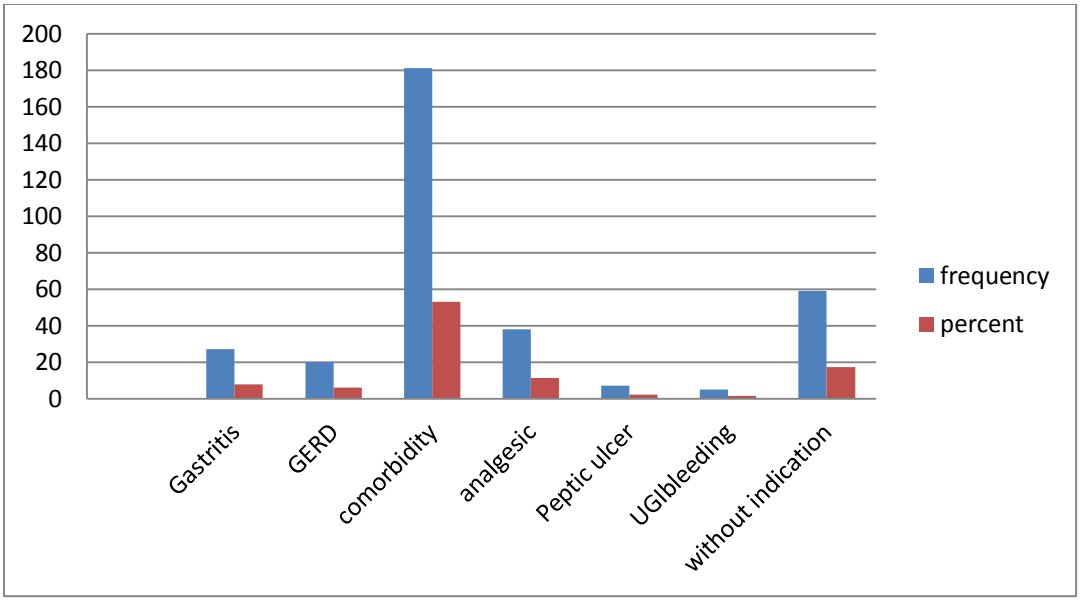
Indication

Out of 341 patients, Indication for giving PPI in 181 Patients were received PPIs for Co-morbidities (53.1%) which was majority followed by Analgesic in 42 patients (12.3%), Gastritis in 27 patients (7.9%), GERD in 20 patients (5.9%), Peptic ulcer in 7 patients (2.1%), UGI bleeding in 5 patients (1.5%). PPIs were administered in the remaining 59 patients (17.3) for without indications.

Table-5: Indication

Indication	Frequency	Percent
Gastritis	27	7.9
GERD	20	5.9
Co-morbidity	181	53.1
Analgesic	42	12.3
Peptic ulcer	7	2.1
UGI bleeding	5	1.5
Without indication	59	17.3

Figure-5: Indication v/s Frequency and percent



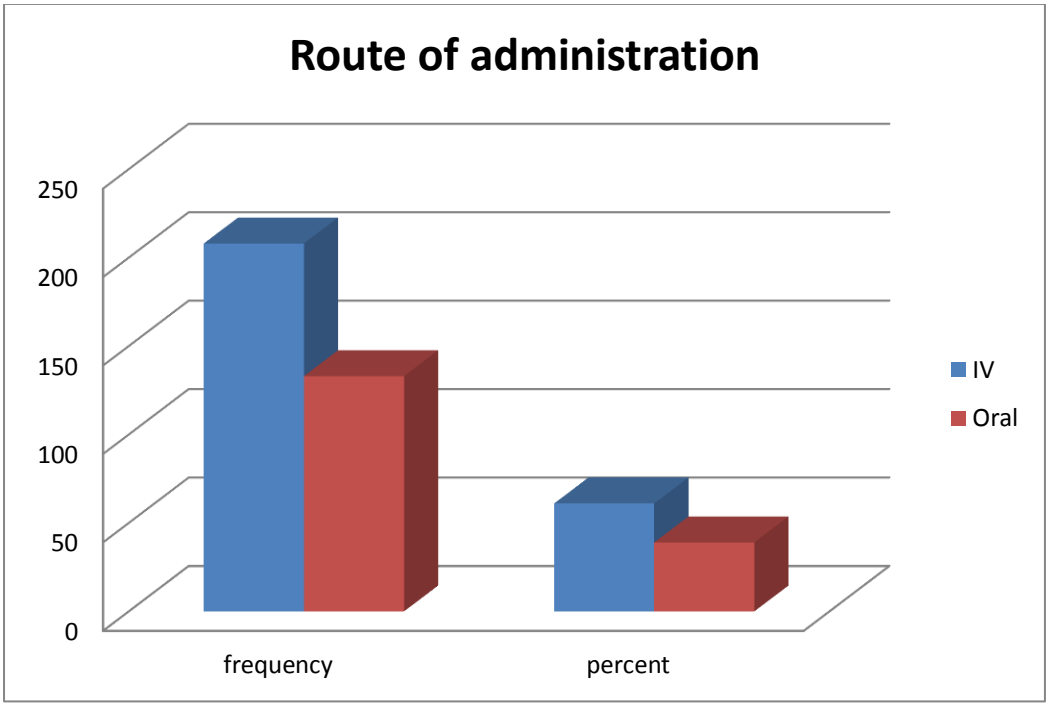
Route of Administration

Out of 341 patients included in the study, the majority of 208 patients were received PPI through intravenous route (61%) and 133 patients received through Oral route (39%).

Table-6: Route of Administration

Route of Administration	Frequency	Percent
IV	208	61.0
Oral	133	39.0

Figure-6: Route of Administration v/s Frequency and Percent



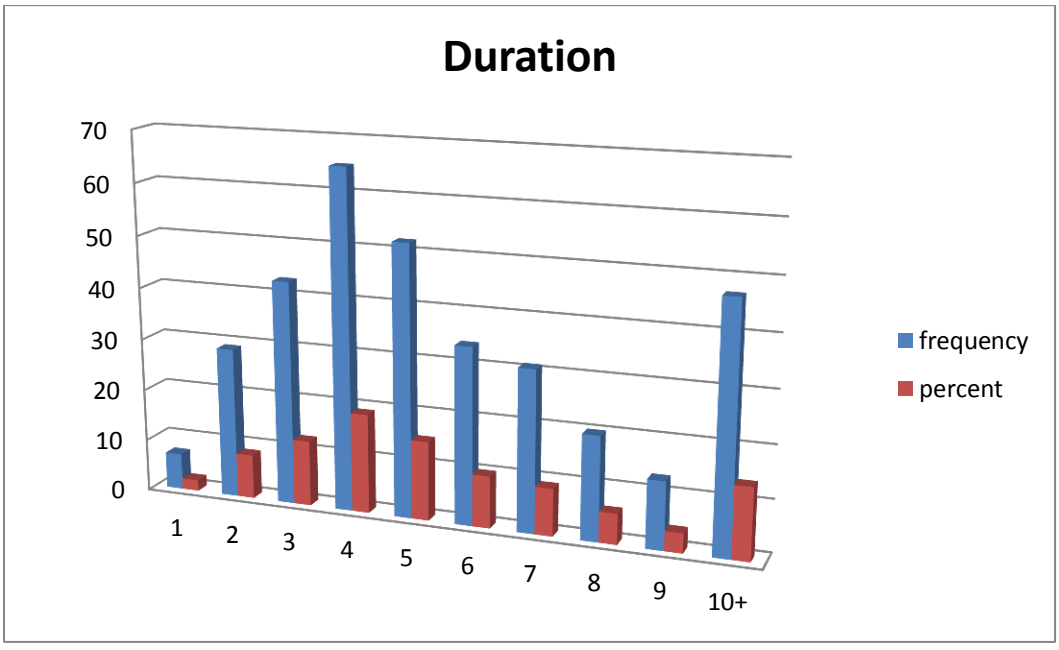
Duration

Among 341 patients in this study, most of the patients received PPI for a duration of 4 days in 65 patients (19.1%) followed by duration of 5 days in 52 patients (15.2%), duration of 3 days in 43 patients (12.6%), duration of 6 days in 34 patients (10%), duration of 7 days in 31 patients (9.1%), duration of 2 days in 29 patients (8.5%), duration of 8 days in 20 patients (5.9%), duration of 9 days in 13 patients (3.8%) and duration of 1 day in 7 patients (2.1%). Remaining 47 patients received PPI for 10 days and above up to 21 days.

Table-7: Duration

Duration (days)	Frequency	Percent
1	7	2.1
2	29	8.5
3	43	12.6
4	65	19.1
5	52	15.2
6	34	10
7	31	9.1
8	20	5.9
9	13	3.8
10+	47	13.8

Figure-7: Duration v/s Frequency and percent



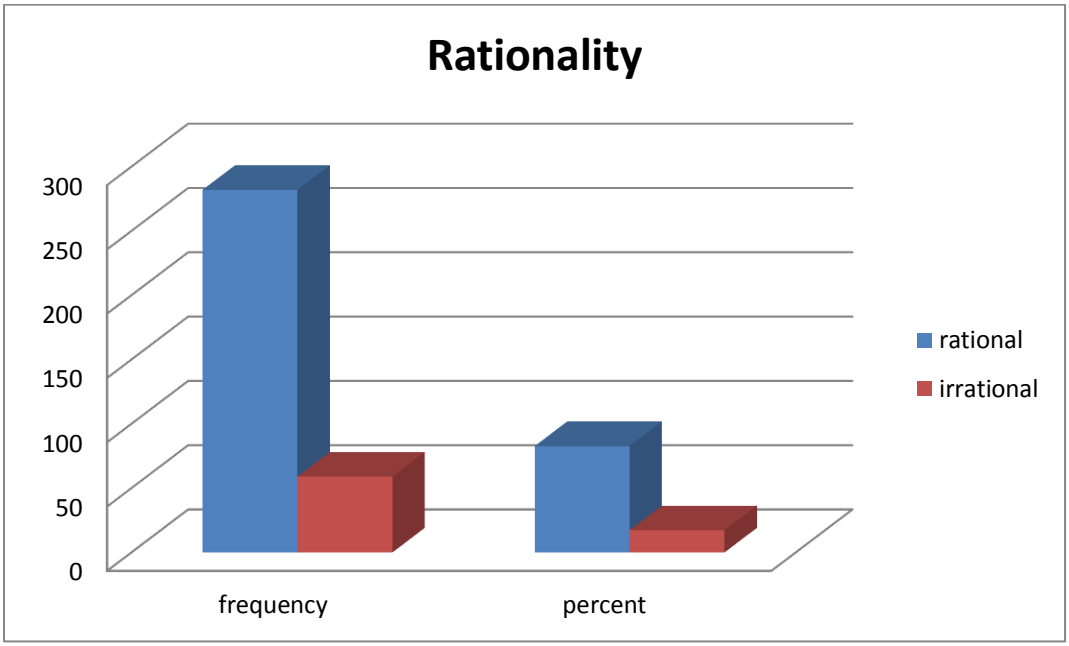
Rationality

Out of 341 patients included, 282 patients received rational therapy (82.7%) and 59 patients received irrational therapy (17.3%).

Table-8: Rationality

Rationality	Frequency	Percent
Rational	282	82.7
Irrational	59	17.3

Figure-8: Rationality v/s Frequency and distribution



COST ANALYSIS

S.No	Generic name	Brand prescribed	Cost of prescribed brand		Other available brands	Cost of available brand		Difference in cost	
			Oral	iv		Oral	iv	Oral	iv
1	Pantoprazole	Pan 40	8.00	44.00	Pantodac	9.60	45.25	+1.60	+1.25
					Pantium	8.70	-	+0.70	-
					Pantocid	8.65	49.76	+0.65	+5.76
2	Esomeprazole	Esomac	6.80	83.00	Raciper	6.80	82.50	0.00	**-0.50**
					Nexpro	7.55	93.40	**-0.75**	+10.4
					Sompraz	6.80	78.50	0.00	**-4.50**
3	Omeprazole	Omez	3.84	31.88	Omicap	4.43	-	+0.60	-
4	Rabeprazole	Rablet 40	9.29	91.95	Veloz 20	6.45	-	**-2.84**	-
		Rabicip	6.80	77.20	Razo 20	7.39	-	**-1.90**	-

Table No: 9

Pan 40 was the brand among pantoprazole which was of least cost available in the hospital. The other available brands; Pantodac, Pantium and Pantocid are costlier than the prescribed brand. Esomeprazole was having other available brands in the hospitalof lesser cost. Brand Reciper injection, Nexpro tablet and Sompraz injection were respectively 0.50, 0.75 and 4.50 rupees lesser than brand Esomac. Among the available 2 brands in Omeprazole, the prescribed brand was Omez which is Rs.0.60 less costly than available Omicap. Rablet 40 and Rabicip were the brands prescribed for the drug Rabeprazole while other lesser brands were available. Veloz 20 and Razo 20 are respectively Rs.2.84 and Rs.1.90 costlier than the prescribed brand.

Pan 40 (Pantoprazole) was seen to be the most prescribed brand in this study. The cost of pan 40 was reasonable compared to the other prescribed brands. However, Omez (Omeprazole) was the prescribed brand with least cost. Brand Esomac (Esomeprazole) and Rablet 40 & Rabicip (Rabeprazole) were the brands having twice the cost than other prescribed brands.

Discussion

DISCUSSION

The majority of patient population was male (69.5%, n=237) with remaining being female (30.5%, n=104). (Table-2). Most of the patients under the study were of age from 41-60 years old (42.8%, n=146) (table-1). (Graph-1), followed by patients who are in the age of above 60 years old (32.6%, n=111) and the remaining of patients was of age of 18-40 years (24.6%, n=84). A similar study was conducted by Rajani, Sathisha Aithal et al and reported that patients of age between 41 to 60 were the majority group of people who received PPIs same as this study. Middle aged group was observed to receive PPIs more than any other age groups.

All patients in the study were selected from two Departments. Among that, 216 patients were from gastroenterology (63.3%) and remaining 125 patients were from Department of surgery (36.7%). Most of the patients were included from the Department of Gastroenterology. (table-3), (Graph-3). It is observed that PPIs were prescribed most in patients admitted in Department of Gastroenterology due to gastric-related issues in them.

Among 341 patients in the study, Pan was administered in 308 patients (90.3%) followed by Rablet in 18 patients (5.3%), Esomac in 10 patients (2.9%), Omez in 4 patients (1.2%) and Rabicip in 1 patient (0.3%). It is observed that a greater extent of patients received Pantoprazole. A similar study done by Rajani, Sathisha Aithal et al also states that Pantoprazole was the most prescribed PPI in their study. Patients who received multiple drug therapy with antibiotics in this study received Pantoprazole as well more frequently for the eradication of *H.Pylori* induced Peptic ulcer disease and as prophylactic agent for NSAID induced PUD.

Out of 341 patients, Indication for giving PPI in 181 Patients were received PPIs for Co-morbidity (53.1%) which was majority followed by analgesic use in 38 patients (11.1%), Gastritis in 27 patients (7.9%), GERD in 20 patients (5.9%), Peptic ulcer in 7 patients (2.1%), UGI bleeding in 5 patients (1.5%). PPIs were administered in the remaining 59 patients (17.3%) for without indications. A similar study was done by Nousheen et al and concluded that most

of the patients received PPIs with NSAIDs. But in this study, PPIs were administered in most of the patients because of co-morbidity. The indication for administering PPIs depends upon the diagnosis and possible issues to be occurred.

The majority of 208 patients out of 341 patients in this study were received PPI through intravenous route (61%) and 133 patients received through Oral route (39%). Rapid onset of action was achieved by administering intravenously. Those patients who received drugs with lesser interacting potential were observed to receive PPIs orally.

Among 341 patients in this study, most of the patients received PPI for a duration of 4 days in 65 patients (19.1%) followed by duration of 5 days in 52 patients (15.2%), duration of 3 days in 43 patients (12.6%), duration of 6 days in 34 patients (10%), duration of 7 days in 31 patients (9.1%), duration of 2 days in 29 patients (8.5%), duration of 8 days in 20 patients (5.9%), duration of 9 days in 13 patients (3.8%) and duration of 1 day in 7 patients (2.1%). Remaining 47 patients received PPI for 10 days and above up to 21 days. The duration therapy depends on the condition and cure rate of the patient received. However, long term administration of PPIs may result in serious.

Out of 341 patients included, 282 patients received rational therapy (82.7%) and 59 patients received irrational therapy (17.3%). A greater extent of patients in this study received considerably a rational therapy. Rational use of PPIs minimizes the potential risks of drug interactions and other possible harm to the subject.

Pan 40 was the brand among pantoprazole which was of least cost available in the hospital. The other available brands; Pantodac, Pantium and Pantocid are costlier than the prescribed brand. Esomeprazole was having other available brands in the hospital of lesser cost. Brand Reciper injection, Nexpro tablet and Sompraz injection were respectively 0.50, 0.75 and 4.50 rupees lesser than brand Esomac. Among the available 2 brands in Omeprazole, the prescribed brand was Omez which is Rs.0.60 less costly than available Omicap. Rablet 40 and Rabicip were the brands prescribed for the drug Rabeprazole while other

lesser brands were available. Veloz 20 and Razo 20 are respectively Rs.2.84 and Rs.1.90 costlier than the prescribed brand. The brands with lesser cost can be administered to achieve a cost effective therapy.

Conclusion

CONCLUSION

Most of the patients in this study received PPIs from the Gastroenterology department because of the Gastric-related disorders. The prescribing pattern has to be further monitored to reduce the long term use of PPIs to bring down interactions and other possible issues related to PPIs.

Pantoprazole was the most prescribed PPI in this study. It was frequently administered for the prophylaxis of NSAID induced peptic ulcer. Pantoprazole shows no significant interactions with other co-administered drugs and it is the PPI available in the hospital with least cost. Hence, it is the best drug of choice because of its lowest interaction potential with other medications as well as in terms of cost. The duration of PPI administration has to be taken in to account as the long term administration may lead to unpredictable issues like hepatic dysfunction and higher treatment cost.

Even though, there are only considerable differences between PPIs in terms of clinical efficacy, the possible drug interactions could be a key factor in the selection of PPIs. In addition, utmost care should be taken while administering PPIs in patients receiving multiple drugs and other elder patients prone to take combination of drugs to attain a rational therapy. PPIs proven to have lower risks of drug interaction would be the favorable choice in those occasions.

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Annexure 1

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

Mr Adam Osman Suliman Abu Musa
II year M Pharm
Department of Pharmacy Practice
Guide: Dr Prudence A Rodrigues
PSG College of Pharmacy
Coimbatore

Ref: Project No.17/153

Date: May 31, 2017

Dear Adam Osman Suliman,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 25.04.2017 to conduct the research study entitled *"A retrospective study on prescribing patterns and cost analysis of proton pump inhibitors"* during the IHEC meeting held on 12.05.2017.

The following documents were reviewed and approved:

1. Project submission form
2. Study protocol (Version 1 dated 25.04.2017)
3. Confidentiality statement
4. Application for waiver of consent
5. Permission letter from concerned Heads of Department
6. Current CVs of Principal investigator, Co-investigator
7. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 12.05.2017 at IHEC Secretariat, PSG IMS & R between 10.00 am and 11.00 am:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Mr R Nandakumar (Chairperson, IHEC)	BA., BL	Legal Expert	Male	No	Yes
2	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	Yes
3	Dr S Shanthakumari	MD	Pathology, Ethicist	Female	Yes	Yes
4	Dr Sudha Ramalingam	MD	Epidemiologist, Ethicist Alt. member-Secretary	Female	Yes	Yes
5	Dr D Vijaya	M Sc., Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
   a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
   b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
   c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
   d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
   e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented
   f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review
7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,

SECRETARY
PSG IMS&R
COIMBATORE-641004.
INSTITUTIONAL HUMAN ETHICS COMMITTEE

Dr S Bhuvaneshwari
Member - Secretary
Institutional Human Ethics Committee

From:

Adam Osman Suliman Abu musa

II year m pharm, Pharmacy practice

PSG college of Pharmacy

To: Dr.L. Venkatakrishnan

HOD of Gastroenterology Department

PSG Hospital and institute.

Respected sir,

RE: Permission for data access

I am Adam Osman Suliman Abu Musa II year m pharm, Pharmacy practice,doing a project work under the title **"A Retrospective Study on Prescribing Patterns and Cost Analysis of Proton Pump Inhibitors".** I need your permission for accessing and collecting data for the targeted patients of the study.

Looking for granting my request.

Thanking you,

Adam Osman

Forwarded & OK

Dr. Venkatakrishnan MD DM DNB AFSA (France)
Prof. HOD of Gastroenterolo
PSG Hospitals
Coimbatore - 6
Reg. No

From:

Adam Osman Suliman Abu musa

II year m pharm, Pharmacy practice

PSG college of Pharmacy

To: Dr. Prem Kumar

HOD of the Surgery Department

PSG Hospital and institute.

Respected sir,

RE: Permission for data access

I am Adam Osman Suliman Abu Musa II year m pharm, Pharmacy practice,doing a project work under the title **"A Retrospective Study on Prescribing Patterns and Cost Analysis of Proton Pump Inhibitors".** I need your permission for accessing and collecting data for the targeted patients of the study.

Looking for granting my request.

Thanking you,

Permitted to do the Study

Adam Osman

Annexure 2

Data collection form

Case no:	Ip/Op No:	Department
Age	Sex	
Admitted on:	Discharged on:	
Complaint at admission:		
Medical history:		
Medication history:		
Drug allergies:		
Diagnosis:		

Brand name	Generic name	Dose&freq	Date							

Indications of PPI	
Patient under upper gastrointestinal endoscopy	
GERD	
Helicobactor pylori reaction	
Peptic ulcer ;gastric/duodenal/bleeding	
NSAIDs and corticosteroid in older patient	
Dyspepsia	
Increase gastric acid/ ZES/ mastocytosis	
Diagnosis of gastritis	
Prevention of drug induced ulcer	
Aspirin and warfarin /coumadin	

PPI name	IV	Oral	Duration	Reason

PPI name	IV	Oral	Duration	Cost

PPI prescribing pattern	Rational		irrational	

Annexure 3

JKKN J.K.K.NATTRAJA COLLEGE OF PHARMACY

JKKN College of Pharmacy

Kumarapalayam - 638183.

INDIA'S TOP 50 PHARMACY COLLEGES 2016 NIRF

Certificate

CEP 10 POINTS

This certificate is awarded to Dr/Mr/Ms/Mrs ADAM OSMAN SULIMAN

has participated as a ~~Resource person~~/Delegate/~~Organizer~~ at the National level seminar on "Role of Clinical Pharmacist in India towards Safe and Better Medicines" on 07.04.2016 Sponsored by Indian Pharmaceutical Association Mumbai, IPA Tamilnadu State Branch & TANIPA Trust and Organized by Indian Pharmaceutical Association Bhavani - Kumarapalayam Local Branch.

Patron | Co-ordinator | Convenor

The Tamilnadu Dr. M.G.R Medical University Chennai has awarded 10 CEP Credit Points for this Seminar.

Society of Nuclear Medicine India (Southern Chapter)
AUGUST 12 & 13, 2017

world Rhenium congress
2nd World Congress on Rhenium
AUGUST 14 & 15, 2017

WTA WORLD THERANOSTICS ACADEMY SINCE 2013
AUGUST 15 & 16, 2017

KMCH
Kovai Medical Center and Hospital

World Theragnostics Academy

15th & 16th August, 2017

Department of Nuclear Medicine and PET CT

Kovai Medical Center and Hospital

Coimbatore

Certificate of Participation

This is to certify that Prof. / Dr. / Mr. / Ms. ....Adam Osman Suliman..... participated in World Theragnostics Academy (WTA) and Workshop held from 15th & 16th of August, 2017 by the Department of Nuclear Medicine and PET CT, Kovai Medical Center and Hospital, Coimbatore as delegate/presented oral paper/poster/trade delegate.

Dr. Ajit Shinto
Organizing Chair

Dr. K.K. Kamaleshwaran
Organizing Secretary